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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/649,108	08/28/00	CHEN	L 07039-220001

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HM22/0918

EXAMINER	
WILSON, M	
ART UNIT	PAPER NUMBER

1633  
DATE MAILED: 09/18/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

**Office Action Summary**

Application No.

09/649,108

Applicant(s)

CHEN, LIEPING

Examiner

Michael Wilson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-5, 11-13, 36 and 37 drawn to DNA, vectors, cells comprising the vectors and methods of making protein classified in class 536, subclass 23.1 and various other classes/subclasses.
  - II. Claims 6-10, 14-16, 17 and 22-24 drawn to polypeptides and methods of stimulating T cells using proteins, classified in class 514, subclass 2.
  - III. Claims 18-21, drawn to a method of stimulating T cells using nucleic acids, classified in class 514, subclass 44.
  - IV. Claims 25-27 and 29-31, drawn to a method of identifying compounds using non-transfected APC in an immunoassay, classified in class 435, subclass 7.1.
  - V. Claims 28 and 32, drawn to a method of identifying compounds of interest using transfected APC in an immunoassay, classified in class 800, subclass 3 or 514/44 and possibly other classes/subclasses.
  - VI. Claims 33-35, drawn to antibodies, classified in class 530, subclass 387.1 .
  - VII. Claims 38 and 39, drawn to fusion proteins, classified in class 530, subclass 402.
  - VIII. Claims 40-44, drawn to nucleic acids encoding fusion proteins, vectors, cells comprising the vectors and a method of making the fusion protein using the cells, classified in 536, subclass 23.1 and various other classes/subclasses.

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2. The inventions are distinct, each from the other because of the following reasons:

Groups I and II are patentably distinct because the DNA can be used as a probe while the proteins can be used to isolate antibodies. The protocols and reagents for DNA and proteins are materially distinct and separate. The DNA does not require the protein and the protein does not require the DNA.

Groups I and III are related as a product and method of using the product. However, the DNA can be used for numerous methods such as to make protein, for gene therapy or as a probe which are all patentably distinct. In addition, the method may be performed with the protein and does not require the DNA. Therefore, the groups are patentably distinct.

Groups I and IV are unrelated because the DNA can be used as a probe while the method is used to identify compounds using T cells and non-transfected APC. The protocols and reagents for DNA and proteins are materially distinct and separate. The DNA does not require the method and the method does not require the DNA.

Groups I and V are related as a product and method of using the product. However, the DNA can be used for numerous methods such as to make protein, for gene therapy or as a probe which are all patentably distinct. In addition, the method may be performed with non-transfected APC that have been incubated with protein and does not require the DNA. Therefore, the groups are patentably distinct.

Groups I and VI are unrelated because the DNA can be used as a probe while the antibody can be used to isolate proteins. The protocols and reagents for DNA and antibodies are materially

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distinct and separate. The DNA does not require the antibody and the antibody does not require the DNA.

Groups I and VII are unrelated because the DNA can be used as a probe while the fusion protein can be used to isolate antibodies. The protocols and reagents for DNA and proteins are materially distinct and separate. The DNA does not require the fusion protein and vice versa.

Groups I and VIII are unrelated because the DNA of Group I makes a patentably distinct protein than that of Group VIII. The DNA encoding the protein and the fusion protein are not taught as being used together. The proteins and fusion proteins are not taught as being used together. The DNAs have different structures and functions. Therefore, Groups I and VIII are patentably distinct.

Groups II and III are patentably distinct because the protein can be used to isolate antibodies while the method is used to stimulate T cells. Group II does not require the consideration of the intracellular machinery expressing the protein to functional levels which is required for the method of Group III. The proteins do not require the method and the method does not require the proteins.

Groups II and IV are patentably distinct because the protein can be used to isolate antibodies while the method of culturing cells as claimed is used to identify compounds of interest. The protein can be used in multiple uses and is not limited to the method of identifying compounds. The proteins do not require the method and the method does not require the protein.

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Groups II and V are patentably distinct because the protein can be used to isolate antibodies while the method is used to identify compounds. The protocols and reagents required for proteins and immunoassays using transfected cells are materially distinct and separate. The proteins do not require the method and the method does not require the protein.

Groups II and VI are patentably distinct because the proteins can be used to stimulate T cells while the antibodies can be used to identify proteins. The protocols and reagents required for proteins and antibodies are materially distinct and separate. The proteins does not require the antibodies and the antibodies do not require the proteins.

Groups II and VII are patentably distinct because the protein of Group II has a different structure and function than Group VII. The specification does not teach that the protein of Groups II and VII have the same function. The protein of Group II is not required for the fusion protein of group VII and vice versa.

Groups II and VIII are patentably distinct because the protein of Group II can be used to isolate antibodies while the nucleic acids of Group VIII can be used to make fusion proteins. The protocols and reagents for proteins and DNA are materially distinct and separate. The protein does not require the DNA and vice versa.

Groups III and IV are patentably distinct because the method of stimulating T cells using APC cultured with proteins and transfected APC require materially distinct protocols and reagents. Transfected APC in the assay require the consideration of intracellular machinery

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expressing protein functionally in the assay which is not required for the method of Group III.

Nor are the methods disclosed as being used together.

Groups III and V because stimulating T cells can be used to treat disease while the method of Group V is used to identify compounds. The protocols and reagents required to treat disease and to identify compounds in immunoassays using transfected cells are materially distinct and separate. The method of stimulating T cells does not require the method of identify compounds and vice versa.

Groups III and VI are patentably distinct because stimulating T cells can be used to treat disease while the antibodies can be used to identify proteins. The protocols and reagents required treat disease and to use antibodies are materially distinct and separate. The method does not require the antibodies and the antibodies do not require the method.

Groups III and VII are patentably distinct because stimulating T cells can be used to treat disease while the fusion proteins can be used to isolate antibody. The protocols and reagents for the method and fusion proteins are materially distinct and separate. The method does not require the fusion protein and vice versa.

Groups III and VIII are patentably distinct because stimulating T cells can be used to treat disease while the nucleic acids of Group VIII can be used to make fusion proteins. The protocols and reagents for the method and DNA are materially distinct and separate. The method does not require the DNA and vice versa.

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Groups IV and V are patentably distinct because the method of Group IV does not require transfected APC which is required for Group V. Transfected APC in the assay require the consideration of intracellular machinery expressing protein functionally in the assay which is not required for the method of Group IV. The methods are not disclosed as being used together. Therefore, the methods are materially distinct and separate.

Groups IV or V and VI are patentably distinct because the method is used to identify compounds while the antibodies can be used to identify proteins. The protocols and reagents required to identify compounds and to use antibodies are materially distinct and separate. The method does not require the antibodies and the antibodies do not require the method.

Groups IV or V and VII are patentably distinct because the method of Groups IV and V is used to identify compounds while the fusion proteins can be used to isolate antibody. The protocols and reagents for the method and fusion proteins are materially distinct and separate. The method does not require the fusion protein and vice versa.

Groups IV or V and VIII are patentably distinct because the method of Groups IV and V is used to identify compounds while the nucleic acids of Group VIII can be used to make fusion proteins. The protocols and reagents for the method and DNA are materially distinct and separate. The method does not require the DNA and vice versa.

Groups VI and VII are patentably distinct because the antibodies can be used to induce an immune response while the fusion protein can be used in T-cell and cytokine assays. The protocols and reagents for antibodies and fusion proteins are patentably distinct and separate.



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The antibodies do not require the fusion proteins and the fusion proteins do not require the antibodies.

Groups VI and VIII are patentably distinct because the antibodies can be used to induce an immune response while the nucleic acids of Group VIII can be used to make fusion proteins. The protocols and reagents for antibodies and DNA are materially distinct and separate. The antibodies do not require the DNA and vice versa.

Groups VII and VIII are patentably distinct because the fusion proteins can be used to isolate antibodies while the nucleic acids of Group VIII can be used to make fusion proteins. The protocols and reagents for fusion proteins and DNA are materially distinct and separate. The fusion proteins do not require the DNA and vice versa.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classifications, the search required for one Group is not required for the other Groups and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Tracey Johnson, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-2982.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 305-0196.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

A handwritten signature in black ink, appearing to read 'M. C. Wilson', with a long horizontal flourish extending to the right.

MICHAEL C. WILSON  
PATENT EXAMINER